

(19)



Europäisches Patentamt
European Patent Office
Office européen des brevets



(11)

EP 1 088 569 B1

(12)

EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention
of the grant of the patent:
13.08.2003 Bulletin 2003/33

(51) Int Cl.7: **A61M 27/00, A61M 1/00,
A61B 19/08**

(21) Application number: **01200016.2**

(22) Date of filing: **14.11.1996**

(54) Portable wound treatment apparatus

Tragbare Wundbehandlungseinrichtung

Appareil portatif de traitement de blessures

(84) Designated Contracting States:
**AT BE CH DE DK ES FI FR GR IE IT LI LU MC NL
PT SE**

(30) Priority: **14.11.1995 GB 9523253**

(43) Date of publication of application:
04.04.2001 Bulletin 2001/14

(62) Document number(s) of the earlier application(s) in
accordance with Art. 76 EPC:
96938357.9 / 0 865 304

(73) Proprietor: **KCI Medical Ltd.
Witney, Oxfordshire OX8 6BH (GB)**

(72) Inventors:

- **Hunt, Kenneth William
Wimborne, Dorset BH21 1TY (GB)**
- **Heaton, Keith Patrick
Poole, Dorset BH14 OQG (GB)**

(74) Representative: **Woodcraft, David Charles et al
Brookes Batchellor
102-108 Clerkenwell Road
London EC1M 5SA (GB)**

(56) References cited:

EP-A- 0 619 105	WO-A-94/20041
GB-A- 1 579 860	US-A- 4 795 435
US-A- 5 437 651	

BEST AVAILABLE COPY

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

EP 1 088 569 B1

Description

[0001] This invention relates to the healing of wounds and, more particularly, to apparatus for stimulating the healing of superficial wounds.

[0002] PCT Application No. GB95/01983 (WO 96/05873) describes apparatus for stimulating the healing of wounds comprising a porous pad which is permeable to fluids for introduction into the wound, a dressing for covering the wound and providing an air-tight seal around the wound, a drainage tube connecting the pad to a suction pump so that negative pressure can be applied to the wound to draw fluids therefrom, and a canister for collecting fluids sucked from the wound. The apparatus described in the above application has proved to be clinically effective but there are some limitations in its use.

[0003] The apparatus described in the above PCT application is effective for treating a wide variety of different types and sizes of wounds. However, it may require the patient to undergo treatment on the apparatus for a long period. In cases where the patient is confined to bed this may not be a major problem, but where the patient is mobile, it means that he or she would be confined for long periods while the treatment takes place.

[0004] An object of this invention is, therefore, to provide apparatus which can be used more conveniently, especially by patients who are reasonably mobile, and which has certain further advantages which will become apparent from the following description.

[0005] The present invention is limited to an apparatus as disclosed in claim 1.

[0006] The closest prior art is disclosed in WO-A-94/20041.

[0007] The preamble of claim 1 reflects the disclosure of said document.

[0008] Controls and indicators indicating the status of the treatment being applied to the wound are preferably located on the upper side of the housing of the apparatus of the invention so that the patient can easily see, e.g. the level of suction pressure being applied and the programme for such treatment.

[0009] The suction pump is conveniently driven by an electric motor and batteries for such motor may be contained within the housing. However, it is generally more convenient to provide a separate housing for the batteries since these can be placed on the belt or harness in such a way as to balance the weight of the housing, preferably in a housing shaped similarly to the housing for the pump and canister. The canister should be removably mounted within the housing, e.g. by means of a latch or similar release mechanism, so that the canister can be readily removed and replaced when full.

[0010] In a portable therapeutic apparatus (in contrast with a static apparatus of the kind described in the above WO-A-96/05873 application which cannot be easily carried by the patient), it is less easy to determine the pressure prevailing at the wound site being treated. This is

because the pressure will depend, in part, upon the hydrostatic height between the pump and the wound being treated and this height may vary during the treatment, depending upon the patient's movements. Apparatus in accordance with the invention overcomes this problem by providing an additional conduit connecting the wound site or an area close thereto to a pressure-detecting means, preferably located in the housing. The pressure-detecting means can be linked to a microprocessor programmed to maintain such pressure within a predetermined range irrespective of the movement of the patient. This can be done by, for example, signalling the pump to increase its speed where the hydrostatic pressure increases between the pump and the wound site or, conversely, reducing its speed where the hydrostatic pressure is reduced. This feature can also be used in a static therapeutic apparatus of the kind described in the above-mentioned PCT application.

[0011] In the apparatus described in the above PCT application, the level of liquid in the canister is monitored by capacitance measurement. It has now been found that a simpler way of determining when the canister is filled is by measuring or detecting the pressure drop across the canister. The pressure drop can be increased by providing a filter barrier in the region of the outlet end of the canister. Thus, when the liquid reaches a level within the canister so as to substantially occlude the filter, a sharp pressure change occurs in the conduit between the canister and the pump. By monitoring this pressure change, the point at which the canister is filled can be accurately determined.

[0012] Additional advantages and features of the present application will become apparent from the following description and accompanying drawings, in which:-

Figure 1 is a schematic layout of an exemplary apparatus,

Figure 2A and B are pictorial representations of the housing of the pump and canister,

Figure 3A and B are pictorial representations of the apparatus supported on a belt and harness respectively,

Figure 4 is an exploded view of the housing showing the contents,

Figures 5A to F show various views of a preferred form of the canister and a section of a multi-lumen tube, and

Figures 6A to D show various views of a foam dressing connector for connecting the housing to the dressing,

Figure 6E shows a section of a modified multi-lumen tube, and

Figures 7A & 7B show a plan and perspective view of a surgical drape for use with the apparatus.

[0013] Referring to the drawings, the portable therapeutic apparatus comprises a housing 210 (best shown

in Figures 2A and 2B), having rounded corners and a side 211 which is concavely curved in order to fit comfortably to the wearer's body. The shaping of the housing with curved surfaces is to avoid sharp corners or edges which could dig into the user or his carer. The upper surface 212 is generally flat and has an LCD screen 213 on which details such as applied pressure can be displayed. Control buttons 214 are provided to adjust pressures and treatment intervals. Provision is made for housing a canister within the housing and a snap release cover 215 is arranged for removing or introducing the canister.

[0014] Figures 3A and 3B show schematically ways in which the housing 210 may be supported on the patient's body. In Figure 3A, the housing is supported on a belt 216 and its weight is balanced by a similarly rounded casing 217 containing a rechargeable battery pack. Figure 3B shows an alternative arrangement in which the housing is supported on a harness 218 and again a battery pack is contained in a housing 219, also supported on the harness.

[0015] Figure 4 shows an exploded view of the housing 210 indicating the main components within the housing. The housing consists of front and rear shell mouldings 1 and 2 having an external belt clip 21 for attachment to a belt or harness.

[0016] Within housing shell 1 is located a suction pump 6 with associated electric motor 6A and the pump is connected by a silicon rubber tube 103 to a canister spigot 7A in a compartment 20 for the canister 100. Also connected to a second canister spigot 7B via a tube 10 is a pressure relief valve 8 and both tubes 103 and 10 are connected via T-connectors T to pressure transducers (not shown). A microprocessor 4 is mounted on a PCB board 5 and a membrane assembly 3 incorporates an LCD indicator and control buttons.

[0017] The apparatus may include means for recording pressures and treatment conditions given to a particular patient which may be printed out subsequently by the physician. Alternatively, the equipment may include a modem and a telephone jack so that the conditions under which the patient has been treated can be interrogated by the physician from a distant station.

[0018] Canister 100 is a push fit into the cavity 20 and its lower end is supported in a cover 30. The cover 30 incorporates fingers 31 which are releasably engageable with lips 32 to hold the canister in position. The canister and the latch mechanism is arranged so that when the latch is engaged, the spigots 7A and 7B are in sealing engagement or abutment with tubular protrusions 33 and 34 formed in the top of the canister.

[0019] The method of operation of the apparatus can be appreciated from the schematic layout in Figure 1, in which the canister 100 is connected via tube 101 to a porous dressing 102 at the wound site. Suction is applied to the wound site via the canister by a tube 103, connected to the pump 6. The pressure in the tube 103 is detected by the transducer 105.

[0020] A second tube 106 is connected to the wound site 102 at one end, and also to a pressure relief valve 8 and to a second transducer 108. Tubes 106 and 101 can be combined in a multi-partitioned tube in a manner to be described later. By means of tube 106 and transducer 108, the pressure at the wound site can be measured or monitored. A filter 109 is placed at or close to the outlet end of the canister 100 to prevent liquid or solid particles from entering the tube 103. The filter is a bacterial filter which is hydrophobic and preferably also lyophobic. Thus, aqueous and oily liquids will bead on the surface of the filter. During normal use there is sufficient air flow through the filter such that the pressure drop across the filter is not substantial.

[0021] As soon as the liquid in the canister reaches a level where the filter is occluded, a much increased negative pressure occurs in tube 103 and this is detected by transducer 105. Transducer 105 is connected to circuitry which interprets such a pressure change as a filled canister and signals this by means of a message on the LCD and/or buzzer that the canister requires replacement. It may also automatically shut off the working of the pump.

[0022] In the event that it is desired to apply intermittent suction to the wound site, a pressure relief valve 8 enables the pressure at the wound site to be brought to atmospheric pressure rapidly. Thus, if the apparatus is programmed, for example, to relieve pressure at 10 minute intervals, at these intervals valve 8 will open for a specified period, allow the pressure to equalise at the wound site and then close to restore the suction. It will be appreciated that when constant suction (or negative pressure) is being applied to the wound site, valve 8 remains closed and there is no leakage from atmosphere. In this state, it is possible to maintain negative pressure at the wound site without running the pump continuously, but only from time to time, to maintain a desired level of negative pressure (i.e. a desired pressure below atmospheric), which is detected by the transducer 105. This saves power and enables the appliance to operate for long periods on its battery power supply.

[0023] Instead of running two separate tubes to the wound site, it is preferable to contain tubes 106 and 101 in a single tube which is connected through the canister. Thus, for example, tubes 103 and 101 may comprise an internal tube surrounded by an annular space represented by tube 106. This is illustrated in Figures 5A to 5F and in a modified form in Figure 6E.

[0024] In an alternative embodiment, the multi-lumen tube may be constructed as shown in Figure 6E. In this embodiment, the internal bore 606 comprises the line 101 (see Figure 1) and is used to extract fluids from the wound site. Air flow (represented by line 106 in Figure 1) passes down conduits 607 located within the walls of the tube. By spacing the conduits 607 at 90° intervals around the tube, the risk of arresting the air flow by kinking or twisting the multi-lumen tube is minimised.

[0025] Figure 5E is a plan view of the top of a preferred

shape of canister, the generally triangular shape in section being chosen to fit better the space within cavity 20 (see Figure 4). Tubular protrusions on the top of the canister are connected internally of the canister with, respectively, conduits 124 and 121 (see sectional view of Figure 5B), thus maintaining a separation between the tubes which are represented by lines 103 and 106 in Figure 1. At the base of the canister, a moulding 125 facilitates connection to a multi-partitioned tube 126 shown in Figure 5E. Tube 126 has a central bore 127 which is sized to fit over a spigot 128 in moulding 125. At the same time, the external wall of tube 126 seals against the inner wall 129 of moulding 125. Thus, compartment 124 will connect with central bore 127 and the compartment 121 will connect with the annular spaces 130 of tube 126. In this way, a conduit 130 corresponds with line 106 and central bore 127 with line 101 as shown in Figure 1.

[0026] The partitioned tube need not continue all the way to the wound site 102, but can be connected to a short section of single bore tube close to the wound site.

[0027] In the event of an air leak in the dressing at the wound site 102, this can be detected by both transducers 105 and 108 reading insufficient negative pressure for a specific time period, and then triggering a leak alarm, i.e. a message on the LCD, preferably also with an audible warning.

[0028] Typically, the pump 6 is a diaphragm pump but other types of pumps and equivalent components to those specifically employed may be substituted.

[0029] Figures 6A to 6D show various views of a connector for attaching the multi-lumen tube at the wound site. Figures 7A and 7B show a plan and perspective view of a surgical drape for attaching the connector to a porous dressing at the wound site. The connector comprises a moulded plastics disc-like cup 601 having a centrally positioned spout 602. The spout 602 is sized to accept, as a closely sliding fit, the end of a multi-lumen tube e.g. of the kind shown in Figures 5F or 6E. In use, a porous dressing is cut to correspond with the extent of the wound and pressed onto the wound as shown in Figure 10 of our above cited PCT application WO 96/05873. Instead of introducing the lumen into the foam dressing, the cup 601 is pressed onto the porous dressing and secured by a surgical drape. However, if desired, the end of the lumen can be passed into the spout and additionally pressed into the foam. A surgical drape such as shown in Figures 7A and 7B, can be used to secure the connector, lumen and dressing. The drape comprises a polyurethane film 701 coated on one side with a pressure-sensitive acrylic resin adhesive. A hole 702 is cut through all layers of the drape and the hole is dimensioned to correspond approximately with the outer cross-section of the spout 602. Film 701 has an overall size which allows it to be adhered to the patient's skin around the wound site, while at the same time, securing the connector to the porous dressing. A sufficient overlap around the wound is provided so that an air-tight cavity

is formed around the wound.

[0030] In an alternative form, the drape can be made in two parts, e.g. by cutting along the line X-X in Figure 7A. With this arrangement, the wound can be sealed by overlapping two pieces of surgical drape so that they overlap each other along a line Y-Y as shown in Figure 6D.

[0031] The surgical drape may include a protective film 703, e.g. of polyethylene, and a liner 704 which is stripped off prior to use to expose the pressure-sensitive adhesive layer. The polyurethane film may also include handling bars 705, 706, which are not coated with adhesive, to facilitate stretching of the film over the wound site. The dressing is preferably a pad of porous, flexible plastics foam, e.g. reticulated, open intercommunicating cellular flexible polyurethane foam, especially of the kind described in the above-mentioned PCT application WO 96/05873.

[0032] Alternatively, a reticulated intercommunicating cellular foam made from flexible polyvinylacetate or polyvinylalcohol foam may be used. The latter is advantageous because it is hydrophilic. Other hydrophilic open celled foams may be used.

[0033] In another method of therapy, the foam dressing may be sutured into a wound after surgery and the foam dressing connected to the pump unit by the multi-lumen catheter. Negative pressure can then be applied continuously or intermittently for a period determined by the surgeon, e.g. from about 6 hours to 4 to 5 days. After this period, the dressing is removed and the wound resutured. This therapy improves the rate of granulation and healing of wounds after surgery.

Claims

1. Apparatus for applying negative pressure to a superficial wound in a mammal which comprises a porous pad (102) of open, intercommunicating cellular flexible foam, a pump (6), a suction tube (101) for connecting the porous pad to the pump (6), a connector for connecting the pad to the suction tube, a surgical drape (701) for forming an air-tight seal over the wound site, over the pad and over the connector, said connector having a spout (602) for connecting to the end of the suction tube (101) remote from the pump (6) to the wound site, **characterized in that** the connector comprises a disc-like cup (601) having its lower face in contact with said porous pad.
2. Apparatus according to claim 1 wherein the porous pad (102) comprises a polyvinyl alcohol foam.
3. Apparatus according to claim 1 or 2 wherein the surgical drape (701) has a hole (702) for the spout (602) to project therethrough.

4. Apparatus according to claim 3 wherein the surgical drape (701) comprises a plastics film which (701) is coated with a pressure-sensitive adhesive for securing the porous pad (102) and connector to the wound.
5. Apparatus according to any one of the preceding claims wherein the suction tube (101) is a multi-lumen tube.

Patentansprüche

1. Vorrichtung zum Ausüben eines Unterdrucks auf eine Oberflächenwunde in einem Säuger, die umfasst: ein poröses Polster (102) aus offenem, eine Verbindung schaffendem, zellförmigem Weichschaum, eine Pumpe (6), eine Saugleitung (101) zum Verbinden des porösen Polsters mit der Pumpe (6), einen Verbinder zum Verbinden des Polsters mit der Saugleitung, eine chirurgische Abdeckung (701) zum Bilden einer luftdichten Abdichtung über der Wundstelle, über dem Polster und über dem Verbinder, wobei der Verbinder einen Ausguss (602) zum Verbinden des von der Pumpe (6) ferngelegenen Endes der Saugleitung (101) mit der Wundstelle aufweist, **dadurch gekennzeichnet, dass** der Verbinder eine scheibenartige Schale (601) umfasst, deren untere Fläche mit dem porösen Polster in Kontakt steht.
2. Vorrichtung nach Anspruch 1, wobei das poröse Polster (102) einen Polyvinylalkoholschaum umfasst.
3. Vorrichtung nach Anspruch 1 oder 2, wobei die chirurgische Abdeckung (701) ein Loch (702) für den Ausguss (602) aufweist, durch das dieser sich hindurch erstreckt.
4. Vorrichtung nach Anspruch 3, wobei die chirurgische Abdeckung (701) eine Kunststofffolie (701) umfasst, die mit einem druckempfindlichen Klebstoff zum Befestigen des porösen Polsters (102) und des Verbinders an der Wunde beschichtet ist.
5. Vorrichtung nach einem der vorangehenden Ansprüche, wobei die Saugleitung (101) eine Multilumenleitung ist.

Revendications

1. Appareil pour appliquer une pression négative sur une plaie superficielle d'un mammifère qui comprend une compresse poreuse (102) en une mousse souple à cellules ouvertes en communication les unes avec les autres, une pompe (6), un tuyau d'as-

piration (101) pour connecter la compresse poreuse à la pompe (6), un connecteur pour connecter la compresse au tuyau d'aspiration, un champ chirurgical (701) pour former un pansement étanche à l'air couvrant le site de la plaie, la compresse et le connecteur, ledit connecteur comprenant une goulotte (602) pour connecter l'extrémité du tuyau d'aspiration (101) à distance de la pompe (6) au site de la plaie, **caractérisé en ce que** le connecteur comprend une coupelle (601) en forme de disque dont la face inférieure est en contact avec ladite compresse poreuse.

2. Appareil selon la revendication 1 dans lequel la compresse poreuse (102) comprend une mousse d'alcool polyvinylique.
3. Appareil selon la revendication 1 ou 2 dans lequel le champ chirurgical (701) a un trou (702) à travers lequel la goulotte (602) fait saillie.
4. Appareil selon la revendication 3 dans lequel le champ chirurgical (701) comprend un film plastique (701) recouvert d'un adhésif sensible à la pression pour assurer le maintien de la compresse poreuse (102) et du connecteur sur la plaie.
5. Appareil selon l'une quelconque des revendications précédentes dans lequel le tuyau d'aspiration (101) est un tube à lumières multiples.

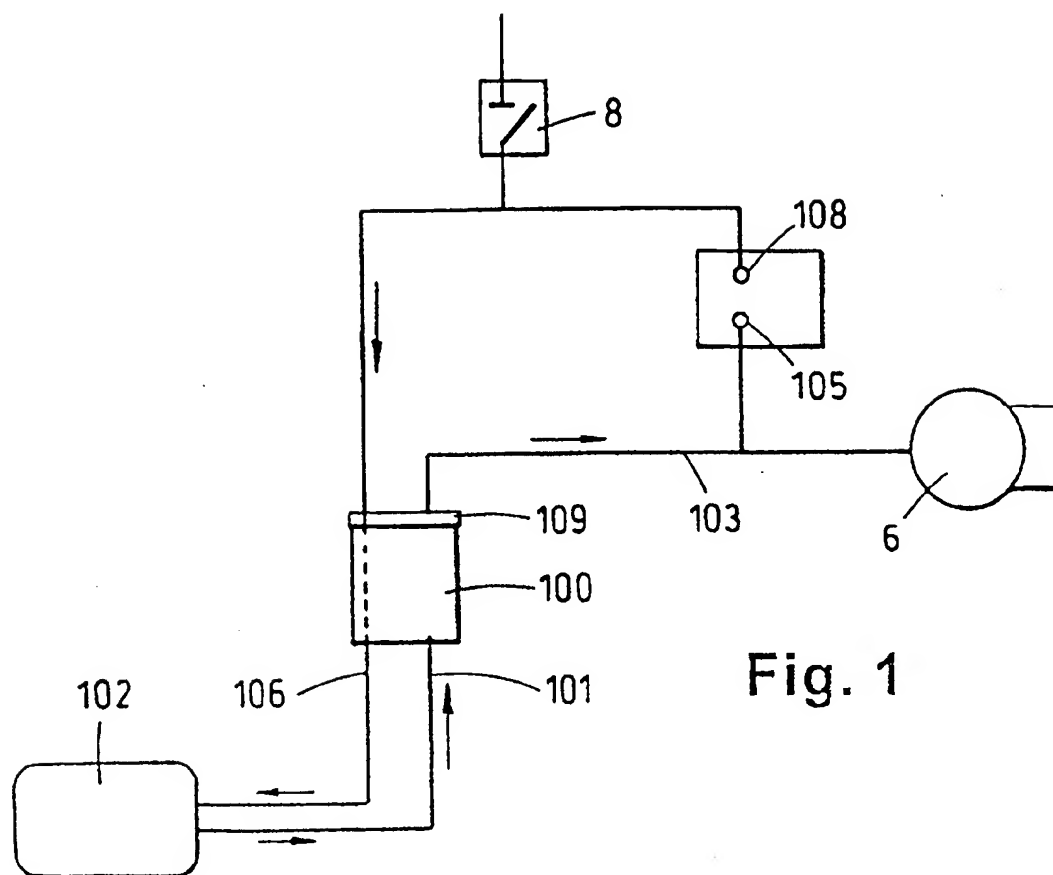


Fig. 1

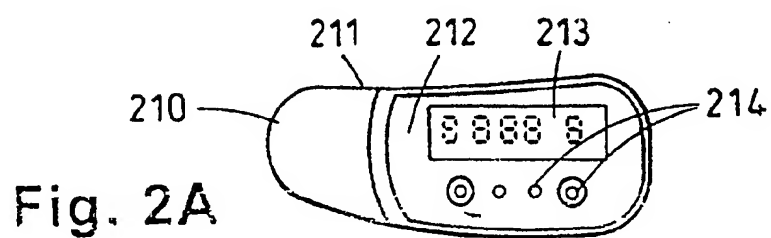


Fig. 2A

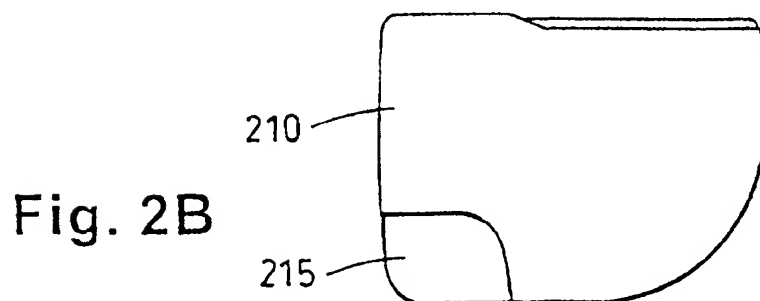


Fig. 2B

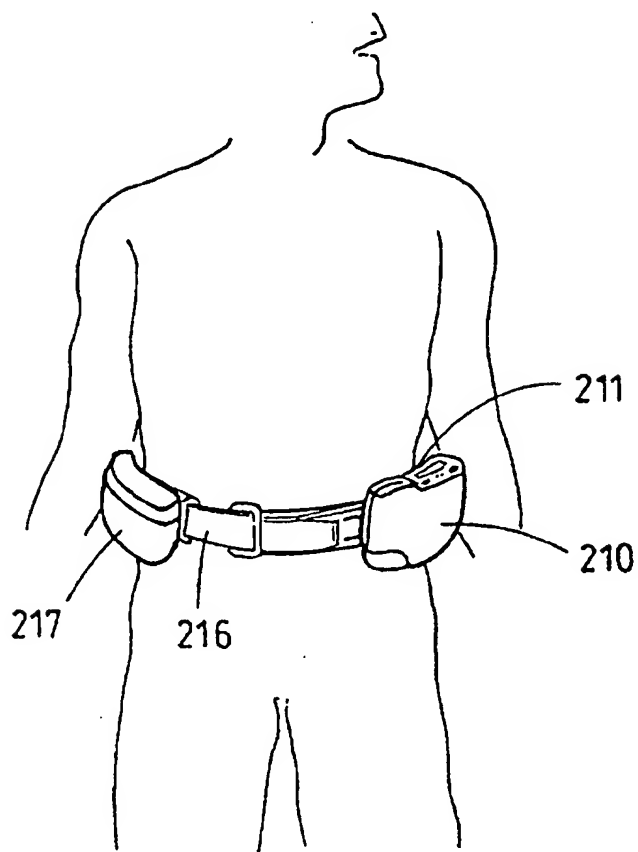


Fig. 3A

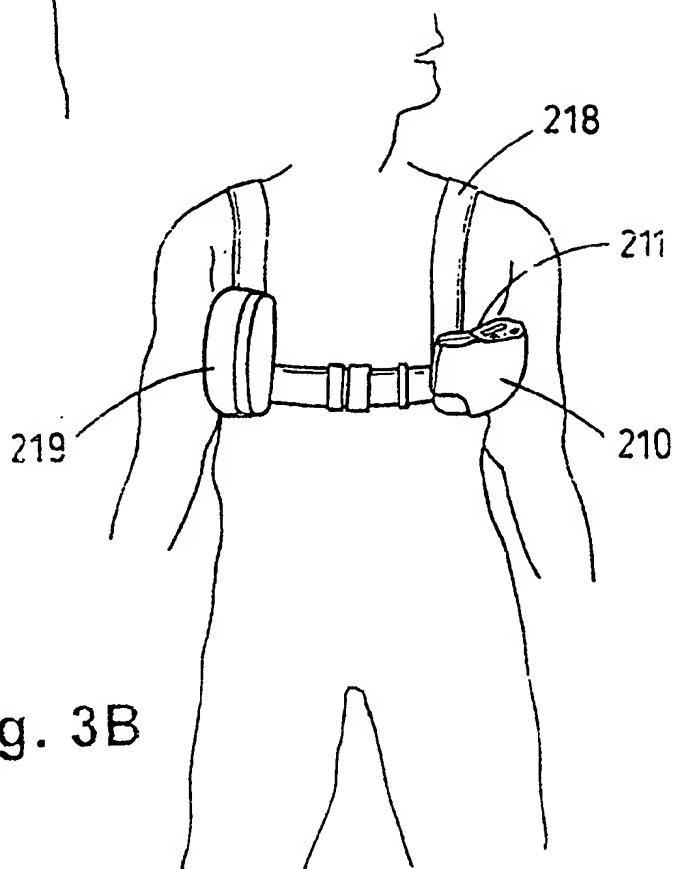


Fig. 3B

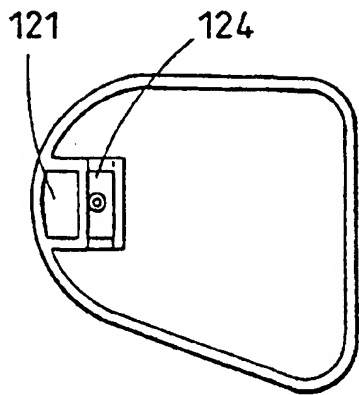


Fig. 5A

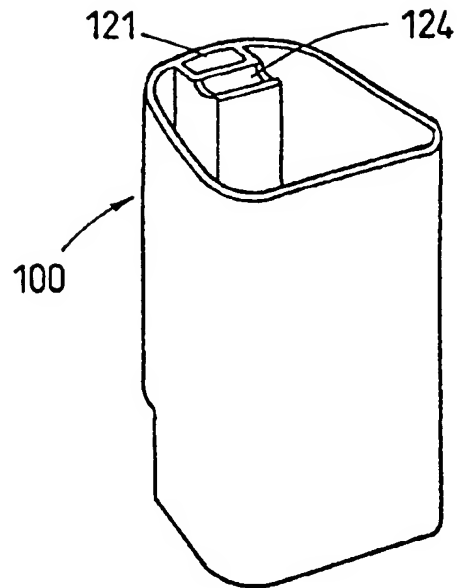


Fig. 5D

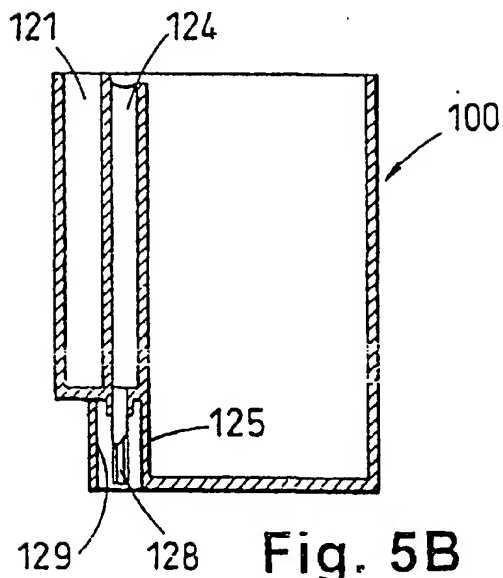


Fig. 5B

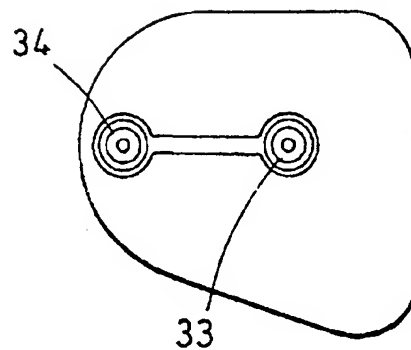


Fig. 5E

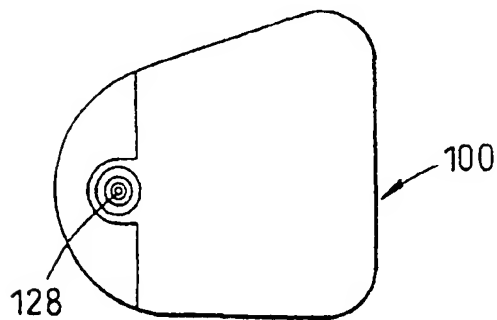


Fig. 5C

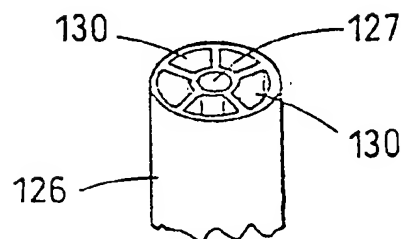


Fig. 5F

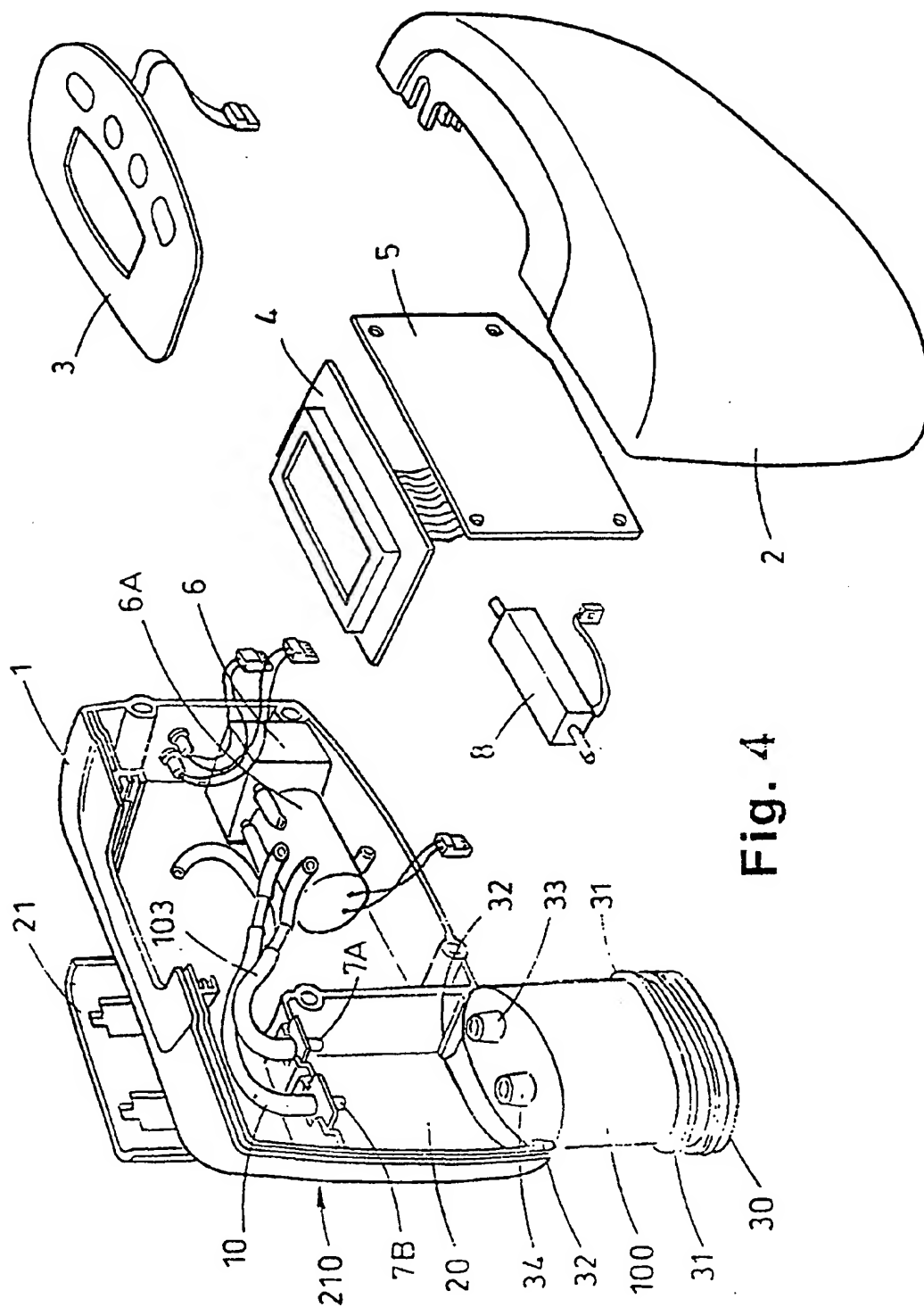


Fig. 4

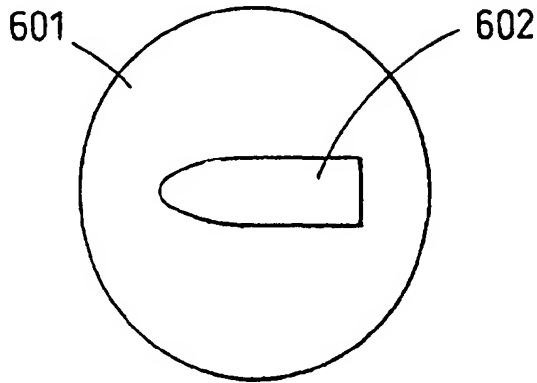


Fig. 6A

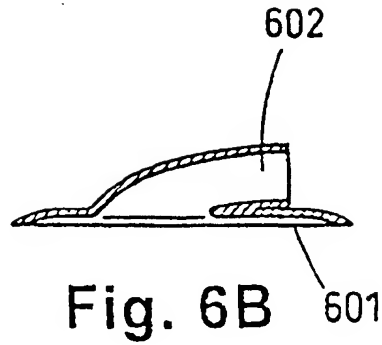


Fig. 6B

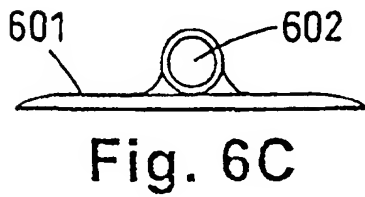


Fig. 6C

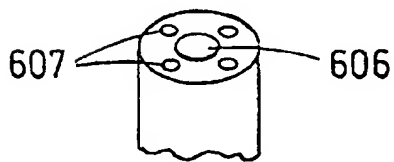


Fig. 6E

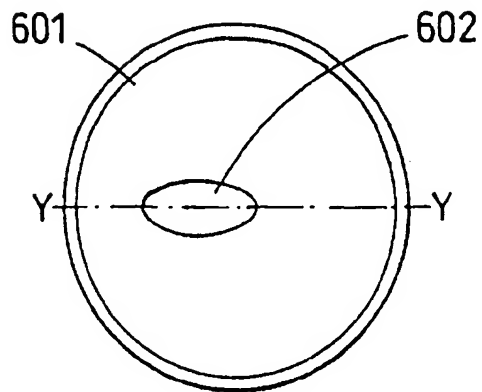


Fig. 6D

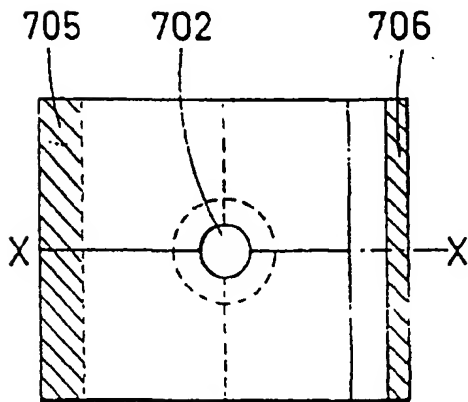


Fig. 7A

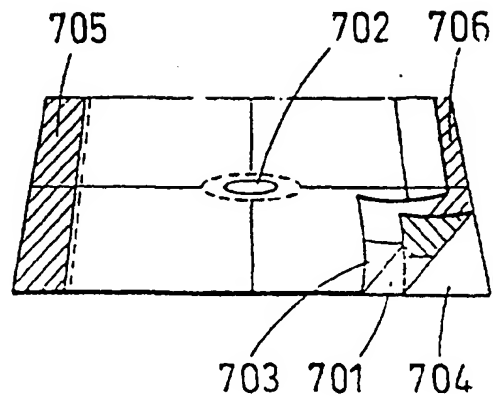


Fig. 7B